

Advisory Action

Application No.
09/132,521

Applicant(s)
Nagai, Y et al.

Examiner
Joseph T. Voitach

Art Unit
1632



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Dec 11, 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) The period for reply expires _____ months from the mailing date of the final rejection.
- b) In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. X A Notice of Appeal was filed on Dec 11, 2001. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. X The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. The proposed amendment(s) will not be entered because:
- (a) they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) they raise the issue of new matter. (See NOTE below);
- (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE:

4. Applicant's reply has overcome the following rejection(s): _____
5. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6. X The a) _____ affidavit, b) _____ exhibit, or c) X request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attached
7. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. X For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
Claim(s) allowed: _____
Claim(s) objected to: _____
Claim(s) rejected: 1-12, 14, and 15
9. The proposed drawing correction filed on _____ a) has b) has not been approved by the Examiner.
10. Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). Deborah Crouch
11. Other: _____

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/6230

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attachment 6(c):

Response to Arguments

35 USC 112, first paragraph

Examiner acknowledges the cancellation of claim 9, however, in view of the unpredictability of gene expression the specification fails to provide the necessary guidance to achieve a substantial amount of biological active CXC-chemokine. Even if a cell were to produce the CXC-chemokine in a detectable amount *in vitro*, the specification fails to provide a nexus between the amount of CXC-chemokine needed to achieve a therapeutic benefit, the proper promoters that should be used to achieve expression, and then the amount of cells need for transplantation wherein all these variables provide the affect of treating HIV infection recited in the preamble of the claims. Therefore, for the reasons above and of record, the rejection is maintained.

35 USC 103

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

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Further, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). When the teachings of the cited references are viewed as a whole CXC-chemokines were being shown to have an effect on HIV infected cells, Sendai virus were known and used as delivery vehicles to express transgenes and to study HIV infection. In view of the teachings of the instant specification there does not seem to be any unexpected results which in view of the teachings of the art as whole the skilled artisan would have a reasonable expectation of success. Therefore, for the reasons above and of record, the rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Crouch, can be reached at (703)308-1126.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Kay Pickney whose telephone number is (703)306-3076.

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Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach



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